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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,084	02/05/2004	Xiaojian Zhao	C0989.70049US01	3297
7590	01/27/2006			
Maria A. Trevisan Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210			EXAMINER WHISENANT, ETHAN C	
			ART UNIT 1634	PAPER NUMBER

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,084	ZHAO ET AL.	
	Examiner Ethan Whisenant, Ph.D.	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 October 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 137-139, 141, 142, 144, 148, 149 and 164-177 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 137-139, 141, 142, 144, 148, 149 and 164, 166-173, and 175-177 is/are rejected.
- 7) Claim(s) 165, 171 and 174 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 February 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>13 JUL 05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

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NON-FINAL ACTION

1. The applicant's Response (filed 17 OCT 05) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 137-139, 141-142, 144, 148-149 and 164-177** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

35 USC § 112- 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

3. **Claim(s) 169, 172-173** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 169 is indefinite because the phrase "the single molecule detection system" lacks proper antecedent basis in Claim 137.

Claim 172 is indefinite because the phrase "the solid support" lacks proper antecedent basis in Claim 137.

Claim 173 is indefinite because the phrase "the solid support" lacks proper antecedent basis in Claim 137.

35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

CLAIM REJECTIONS UNDER 35 USC § 102

6. **Claim(s) 137-139, 141-142, 148, 164, 166-168, 170, 175-176** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Landegren et al. [US 4,988,617 (1991)].

Landegren et al. teach a method for detecting a mutant polymer comprising all of the limitations recited in Claims 137-139, 141-142, 148, 164, 166-168, 170, 175-176.

As regards the newly added limitation (i.e. the polymer is not *in vitro* amplified) please note Landegren et al. in Column 4, beginning at about line 51 wherein these authors teach "The assay may

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be performed with test DNA derived from purified genomic DNA or may be performed *in situ* with the test DNA present in cells."

Claim 164 is drawn to an embodiment of Claim 137 wherein the method further comprises a column purification step. Note that Landegren et al. teach that the oligonucleotides used in their method are purified via columns.

Claim 170 is drawn to an embodiment of Claim 137 wherein the first and second detectable labels are provided as molecular beacon probes. As regards the phrase "molecular beacon" in Claim 170, the examiner asserts that the probes used by Landegren et al. can be termed "molecular beacons." Please note that while the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Guens*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

7. **Claim(s) 137-139, 141-142, 144, 148-149, 164, 166-168, 170, 172-173, 175-177** is/are rejected under 35 U.S.C. 102(e) as being anticipated by Bao et al. [US 2003/0129611(2003)].

Bao et al. teach a method for detecting a mutant polymer comprising all of the limitations recited in Claims 137-139, 141-142, 144, 148-149, 164, 166-168, 170, 172-173, 175-177.

As regards the newly added limitation (i.e. the polymer is not *in vitro* amplified) note that Bao et al. teach the *in situ* detection of mRNA. See at least for example paragraph [0010].

35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of

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each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 103

10. **Claim(s) 169** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. [US 2003/0129611(2003)].

Claim 169 is drawn to an embodiment of Claim 137 wherein unbound detectable labels are not removed prior to analysis.

Bao et al. teach a method for detecting a mutant polymer comprising all of the limitations recited in Claim 169 except these authors do not explicitly teach an embodiment of their method wherein unbound detectable labels are not removed prior to analysis. However, these authors do teach "In theory, molecular beacons do not require a washing step and so should be directly usable in living cells (Matsuo, 1998; Sokol et al., 1998)." Based on these findings and absent an unexpected result it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed in Bao et al. wherein unbound detectable labels are not removed prior to the detection of coincident probe binding. The ordinary artisan would have been motivated by the teachings in Matsuo and Sokol et al. as described in Bao et al.

CLAIM OBJECTIONS

11. **Claim(s) 165, 171, 174** is /are objected to because it/they is/are dependent upon a rejected independent base claim.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

12. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection.

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CONCLUSION

13. **Claim(s) Claim(s) 137-139, 141-142, 144, 148-149 and 164-177** is/are rejected and/or objected to for the reason(s) set forth above.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

The Central Fax number for the USPTO is (571) 273-8300. Before faxing any papers, please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



**ETHAN WHISENANT
PRIMARY EXAMINER**

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